

III. Remarks

This Amendment is being submitted in response to the Final Office Action dated March 31, 2008 and the Advisory Action mailed August 1, 2008. Applicants also respectfully request that the Examiner consider the documents submitted with the enclosed Supplemental Information Disclosure Statement and the references previously submitted with the Supplemental Information Disclosure Statements submitted to the USPTO on June 25, 2008 and March 28, 2008.

A. Status of the Claims

Claims 1-4, 6, 8, 14-17 and 21 are cancelled without prejudice or disclaimer of Applicants' right to pursue subject matter of those claims in one or more divisional applications. Claims 5, 7, 9-13, 18-20 and 22-47 are pending. Applicants have herein amended claims 5, 9, 12, 13, 18, 37 and 42.

Claim 5 has been amended to delete the term "general" as helpfully suggested by the Examiner. Also, claim 5 has been further amended to delete reference to "indol-2yl". Additionally, with regard to the proviso "R4 is a group represented by Formula II", claim 5 has also been amended to delete the reference to "R4 is a group represented by Formula II". These amendments are made for clarification purposes only and do not narrow the scope of the claim.

Support for the amendment to claim 5 can be found for example in the original specification, page 10, lines 8-9, and original claim 6 of the English translation of the specification as filed.

Claim 37 has been amended to delete the term "general" as helpfully suggested by the Examiner. Claim 37 has also been amended such that the term "optionally substituted phenyl or monocyclic aromatic heterocycle" has been replaced with "a substituted or

unsubstituted phenyl or monocyclic aromatic heterocycle”. Claim 37 has also been amended to replace the term “can be the same or different and can be selected...” with the term “independently selected..” These amendments are also made for clarification purposes only and do not narrow the scope of the claim.

The term “optionally substituted” has been deleted from amended claims 5, 12, 37 and 42 and replaced with the synonymous term “substituted or unsubstituted” for clarification and does not narrow the scope of these claims.

B. Rejection under 35 U.S.C. § 112, second paragraph

In the Office Action, the Examiner rejected claims 5 and 37 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner indicated that the term “general” with regard to Formula (V) is ambiguous... [and] should be deleted (See: Office Action, page 2, item 3, third paragraph). In response, the term “general” has been deleted from independent claims 5 and 37. This amendment is being made for clarification purposes only and does not narrow the scope of the claims.

The Examiner also indicated that the proviso “indol-2yl” is confusing. The Examiner stated that “the Ar² element in claims 5 and 37 have been defined to be optionally substituted phenyl or monocyclic aromatic heterocycle, this scope would not have encompassed any indolyl moiety” (See: Office Action, page 2, item 3, fourth paragraph). In response, the proviso “that indol-2yl is excluded” has been deleted from claims 5 and 37. This amendment is being made for clarification purposes and does not narrow the scope of the claim.

The Examiner further indicated that “in claim 5, the R⁴ moiety has been limited to Formula II, therefore, the condition of R⁴ being Formula II in the definition of Ar² what it cannot be is always enforced” (See: Office Action, page 2, item 3, paragraph 5). In response, the proviso “R⁴ is a group represented by Formula II” has been deleted from claim 5. This amendment is being made for clarification purposes and does not narrow the scope of the claim.

Finally, the Examiner indicated that “it is unclear whether claim 37 is within the scope of claim 5 or contains new matter because in claim 37, the phenyl or monocyclic aromatic heterocycles are optionally substituted without limitation while the Ar² when R⁴ is formula II must be substituted with one or more groups selected from lower alkyl, -CO-lower alkyl, -COO-lower alkyl, -OH, -O-lower alkyl, -OCO-lower alkyl, and halogen” (See: Office Action page 2, item 3 last paragraph to page 3, first paragraph). The Examiner has requested that the scope of the claims be clearly defined with explicit antecedent basis pointed out from the specification.

In response, Applicants respectfully submit that claim 37 as amended differs in scope from amended claim 5 in that R³ in claim 37 has been further limited to “a substituted or unsubstituted thienyl”, whereas R³ in claim 5 is “aryl or monocyclic aromatic heterocycle, each of which may be substituted”. The Examiner is respectfully directed to the difference in claims 5 and 37. With respect to claim 5, it is only when R³ is aryl or pyridyl that Ar² cannot be phenyl or pyridyl (See: claim 5). On the other hand, the proviso “that when R³ is aryl or pyridyl... then Ar² is not be phenyl or pyridyl...” is not recited in claim 37 as R³ in claim 37 can only be a substituted or unsubstituted thienyl.

To address the Examiner’s request that the scope of the claims be clearly defined with explicit antecedent basis pointed out from the specification, Applicant respectfully submits the following remarks, with enclosed Appendices Appendix A1-A5 for the Examiner’s convenience:

Support for Formula (V) recited in independent claims 5 and 37 can be found for example in the English translation of the original specification at page 9, line 21 to page 10, line 1, and original claim 5 (See: Appendix A1).

Support for Ar^2 as recited in independent claims 5 and 37 (" Ar^2 : a substituted or unsubstituted phenyl or monocyclic aromatic heterocycle") can be found for example in the English translation of the original specification at page 10, lines 8-9, and original claim 6 (See: Appendix A2).

Support for R^3 as recited in independent claim 5 (" R^3 : aryl or monocyclic aromatic heterocycle, each of which may be substituted") can be found for example in the English translation of the original specification at page 10, line 5, referencing R^1 at page 6, lines 17-18, and original claim 5 (See: Appendix A3).

Support for R^3 as recited in independent claim 37 (" R^3 : a substituted or unsubstituted thienyl") can be found for example in the English translation of the original specification at page 10, line 22 to page 11, line 1, and original claim 7 (See Appendix A4).

Support for R^4 as recited in independent claims 5 and 37 (" R^4 : a group of Formula (II)") can be found for example in the English translation of the original specification at page 10, lines 6-7, referencing R^2 at page 6, line 19 to page 7, line 20, also at page 11, lines 7-11, and original claims 5 and 7 (See: Appendix A5).

Support for X, m and n as recited in independent claim 37 (" X is $\text{C}(\text{R}^{27})\text{R}^{28}$ or NR^{26} and $m=n=2$ ") can be found for example in the English translation of the original specification at page 11, 17-18 (See: Appendix A4).

Support for R^{20} , R^{21} , R^{22} , R^{23} , R^{26} , R^{27} , and R^{28} can be found for example in the English translation of the original specification at page 7, 10-20 (See: Appendix A5).

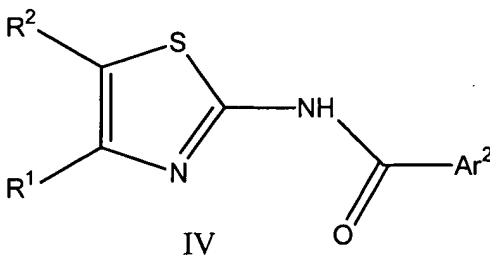
In view of the amendments and support presented above, Applicant respectfully requests that the Examiner's § 112 rejections be withdrawn.

C. Rejection under 35 U.S.C. § 102(a) over Muto, et al.

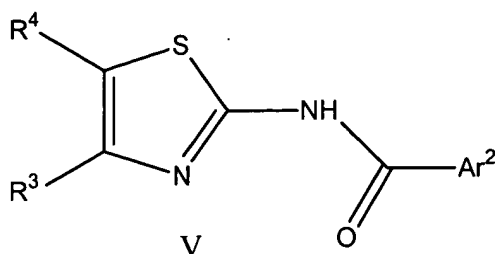
In the Office Action, the Examiner rejected claims 5, 7, and 9-11 under 35 U.S.C. § 102(a) over Muto et al. CA 137 corresponding to published WO 02/049632. The Examiner indicated that "in the two translations of the priority documents, the Markush scope of the instant claims was not embraced since elements R^{20} , R^{21} , R^{22} , R^{23} , R^{26} , R^{27} , or R^{28} , are not found and the scope of these elements are not consistent with the definition of the priority documents as R^{3-6} . Therefore, the benefit of priority date cannot be granted and the rejection is proper." (See: Office Action, page 3, item 3).

This rejection is respectfully traversed. With regard to the Examiner's assertion that "the Markush scope of the instant claims was not embraced since elements R^{20} , R^{21} , R^{22} , R^{23} , R^{26} , R^{27} , or R^{28} , are not found and the scope of these elements are not consistent with the definition of the priority documents as R^{3-6} ", Applicants respectfully direct the Examiner's attention to the priority documents as follows:

JP priority documents 2002-10413 and JP 2002-10447 both disclose 2-acylaminothiazole derivatives represented by Formula IV (See: page 10, line 1 of JP 2002-10413 and page 9, line 17 of JP 2002-10447):



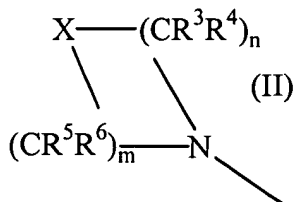
Similarly, amended independent claims 5 and 37 (Formula V) of the present invention recite 2-acylaminothiazole derivative (See: page 10, line 1):



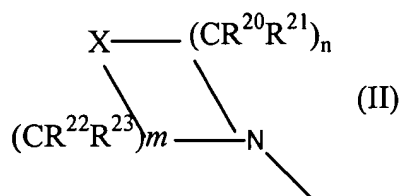
Both Formula IV as disclosed in both priority documents and Formula V recited in amended claims 5 and 37 of the present invention are identical with the exception that the “R” substituents contained at the 4 and 5 positions of the thiazole ring are respectively labeled R¹ and R² in the priority documents (Formula IV) and R³ and R⁴ in the present application (Formula V). As can be seen from the illustration of Formula (IV) in both priority documents and Formula (V) of the present claims, R² and R⁴ are both located at the 5 position of the thiazole ring. Accordingly, Applicant respectfully submits that the scope of the R² substituent corresponds to the scope of the R⁴ substituent.

1. Scope of substituents R²⁰-R²³:

JP priority documents 2002-10413 and JP 2002-10447 both disclose R² represented by, *inter alia*, group (II):



Amended independent claims 5 and 37 recite, *inter alia*, R⁴ represented by the formula (II):



Both Formula II disclosed in the priority documents and Formula II recited in amended claims 5 and 37 of the present invention are identical with the exception that the “R” substituents described by Formula II of the priority documents are labeled R³, R⁴, R⁵ and R⁶ and the “R” substituents described by Formula II as recited in amended claims 5 and 37 of the present invention are labeled R²⁰, R²¹, R²² and R²³. Accordingly, Applicant respectfully submits that the scope of the R³ and R⁴ substituents described by the “(CR³R⁴)_n” group of Formula II disclosed in both JP priority documents correspond to the scope of the R²⁰ and R²¹ substituents described by the “(CR²⁰R²¹)_n” group of Formula II recited in amended claims 5 and 37. In addition, Applicant respectfully submits that scope of the R⁵ and R⁶ substituents described by the “(CR⁵R⁶)_m” group of Formula II disclosed in both JP priority documents correspond to the scope of the R²² and R²³ substituents described by the “(CR²²R²³)_m” group of Formula II recited in amended claims 5 and 37.

In addition to the scope of substituents R³-R⁶ of Formula II disclosed in both JP priority documents corresponding to substituents R²⁰-R²³ of Formula II recited in amended claims 5 and 37 of the present invention, Applicant respectfully submits that the scope of substituents R²⁰-R²³ is also consistent with the scope of substituents R³-R⁶. To illustrate consistency of the scope of these substituents, Applicant directs the Examiner’s attention to Table I in the enclosed Appendix B.

Applicants submit the following comparison of the R³-R⁶ Markush group in both priority documents with the corresponding R²⁰-R²³ Markush group recited in amended claims 5 and 37:

The term “optionally substituted aralkyl” in the respective priority documents, page 8, lines 15-16 of JP App. 2002-10447 and page 9, lines 3-4 of JP App. 2002-10413, is synonymous with the term “optionally substituted arylalkyl” at page 7, lines 12-13 of the English translation of the specification as filed and as recited in amended claims 5 and 37.

The term “optionally substituted heteroarylalkyl” in the respective priority documents, page 8, lines 16-17 of JP App. 2002-10447 and page 9, lines 4-5 of JP App. 2002-10413, is synonymous with the term “optionally substituted aromatic heterocyclic alkyl” at page 7, lines 13-14 of the English translation of the specification as filed and as recited in amended claims 5 and 37.

In view of the arguments presented above, it is respectfully submitted that the scope of substituents R^3 - R^6 of Formula II disclosed in both JP priority documents and corresponding substituents R^{20} - R^{23} as claimed in amended claims 5 and 37 of the present invention are the same. Accordingly, Applicants respectfully request that the Examiner’s 102(a) rejection be withdrawn.

2. Scope of substituents R^{26} - R^{28} :

Priority documents JP 2002-10413 and JP 2002-10447 disclose Formula (II), wherein X is a group represented by, *inter alia*, $N(R^9)$, or $C(R^{10})(R^{11})$. Similarly, amended independent claims 5 and 37 recite, *inter alia*, “X is a group represented by $N(R^{26})$, or $C(R^{27})R^{28}$.” Applicant respectfully submits that the scope of the groups “ $N(R^9)$ ” and “ $C(R^{10})(R^{11})$ ” disclosed in the priority documents in Formula II are identical to the scope of the groups “ $N(R^{26})$ ” or “ $C(R^{27})R^{28}$ ” recited in Formula II of amended claims 5 and 37.

In addition to the scope of substituents R^9 - R^{11} of Formula II disclosed in both JP priority documents and substituents R^{26} - R^{28} of Formula II recited in amended claims 5 and 37 being identical, Applicant respectfully submits that the scope of substituents R^{26} - R^{28} is also consistent with the scope of substituents R^9 - R^{11} . To illustrate consistency of the scope of these substituents, Applicant directs the Examiner's attention to Table II in the enclosed Appendix C.

Upon comparison of the R^9 - R^{11} Markush group in both priority documents with the R^{26} - R^{28} Markush group recited in amended claims 5 and 37, the only differences are as follows:

The term "optionally substituted aralkyl" in the respective priority documents, page 8, lines 15-16 of JP App. 2002-10447 and page 9, lines 3-4 of JP App. 2002-10413, is synonymous with the term "optionally substituted arylalkyl" at page 7, lines 12-13 of the English translation of the specification as filed and as recited in amended claims 5 and 37.

The term "optionally substituted heteroarylalkyl" in the respective priority documents, page 8, lines 16-17 of JP App. 2002-10447 and page 9, lines 4-5 of JP App. 2002-10413, is synonymous with the term "optionally substituted aromatic heterocyclic alkyl" at page 7, lines 13-14 of the English translation of the specification as filed and as recited in amended claims 5 and 37.

In view of the arguments presented above, it is respectfully submitted that the scope of substituents R^9 - R^{11} of Formula II disclosed in both JP priority documents and substituents R^{26} - R^{28} as claimed in amended claims 5 and 37 of the present invention are the same. Accordingly, Applicants respectfully request that the Examiner's 102(a) rejection be withdrawn.

3. Affidavit of Mr. Kimizuka

In response to the Examiner's request that the numerical representation of R²⁰-, R²³ and R²⁶-R²⁸ of the English translation of the specification of the present invention are identical to numerical representations R³-R⁶ and R⁹-R¹¹ of the priority documents and more importantly that the claims of the present invention are entitled to priority within the context of 35 U.S.C. § 119 and are supported by both Japanese priority documents, we have enclosed herewith the Affidavit of Mr. Tetsuya Kimizuka, Japanese IP Attorney for the Applicant, Astellas. Mr. Kimizuka specifically states that:

I hereby declare that support for the numerical representations of Markush elements R²⁰, R²¹, R²², R²³, R²⁶, R²⁷, and R²⁸ recited in independent claims 5 and 37 of the present invention can be found, for example, at page 7, lines 10-20 of the English translation of the present application as filed, and at page 6, line 19 to page 7, line 8 of the Japanese priority document JP 2002-10413 (corresponding to page 8, line 18 to page 9, line 11 of the English translation of Japanese priority document JP 2002-10413) and page 6, line 19 to page 7, line 8 of the Japanese priority document JP 2002-10447 (corresponding to page 8, line 10 to page 9, line 3 of the English translation of Japanese priority document JP 2002-10447).

In this regard the Examiner's attention is drawn to the fact that in an abundance of caution independent claims 5 and 37 have been modified to remove the term "optionally substituted" with respect to the lower alkenyl and lower alkylidene groups for each of R²⁰, R²¹, R²², R²³, R²⁶, R²⁷, and R²⁸. The term "optionally substituted" was removed because, while support for this term is found in the English translation of the International (PCT) application as filed, this term is not found within the Japanese priority documents. Furthermore, independent claims 5 and 37 have been amended to remove the term "cycloalkyl" with respect to the carbamoyl or amino recited therein. The term "cycloalkyl" is found in a different location in the English translation of the International (PCT) application (after the term "lower alkyl" on page 7, line 19 of the English translation) as compared to the priority documents where the term is found at page 9, line 2 and page 9, line 10 of the English translations of JP 10447 and JP 10413, respectively. By making these changes it is respectfully submitted that every word in

claims 5 and 37 as currently amended finds support in the International (PCT) application and both Japanese priority documents.

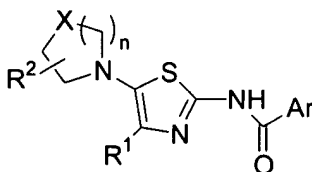
In view of the Affidavit of Mr. Kimizuka and the explanation above, it is respectfully request that the Examiner's 102(a) rejection be withdrawn.

D. Rejection under 35 U.S.C. § 102(e), (f) or (g) over U.S. 2004/0077697

In the Office Action, the Examiner rejected claims 5, 7, 9-13, and 18-47 under 35 U.S.C. §102(e), (f) and (g) over U.S. 2004/0077697. The Examiner indicated that the '697 publication has a filing date prior to the filing date of the instant application. The Examiner also indicated that "abandoning a claim to the same invention... will resolve the issues under 35 U.S.C. § 102(e) and (g)..., but it does not resolve the 102(f) issue." The Examiner further asserted that "the assignee is required to make it of record by stating which entity is the first inventor of the subject matter upon presentation of such evidence." (See: Office Action, page 3, item 4).

It is respectfully submitted that the indicated overlap between the present claims and the structures described in the '697 publication is a misunderstanding. As originally filed, and as currently presented, the proviso in claim 5 specifically excluded the possibility of overlap with the '697 publication. In particular, the proviso excluded verbatim the definition of R¹ in the '697 publication (which corresponds to the 4-position on the thiazole ring, as R³ in Applicant's case). Therefore, none of Applicant's compounds are described in the '697 publication.

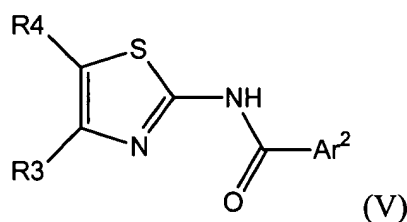
The '697 publication discloses compounds of Formula I:



wherein Ar represents phenyl or pyridyl each of which can be substituted with one or more groups selected from the group consisting of lower alkyl, -CO-lower alkyl, -COO-lower alkyl, -OH, -O-lower alkyl, -OCO-lower alkyl, and halogen (See: page 2, paragraph [0018] of the '697 publication, attached hereto as Appendix D).

The '697 publication also discloses R¹ represents aryl or pyridyl, each of which can be substituted with one or more groups selected from the group consisting of lower alkyl, -CO-lower alkyl, -COO-lower alkyl, -OH, -O-lower alkyl, -OCO-lower alkyl, and halogen (See: page 2, paragraph [0019] of the '697 publication, attached hereto as Appendix D).

Claim 5 of the present invention recites, in pertinent part, a 2-acylaminothiazole derivative represented by Formula V or a pharmaceutically acceptable salt thereof:



Similar to the Ar substituent disclosed in the '697 publication, Ar² in present independent claim 5 can also encompass a phenyl or pyridyl group. However, in contrast to the disclosure of the '697 publication, the proviso recited in independent claim 5 of the present invention does not permit Ar² to be phenyl or pyridyl when R³ is aryl or pyridyl, each of which can be substituted with one or more groups selected from the group consisting of lower alkyl, -CO-lower alkyl, -COO-lower alkyl, -OH, -O-lower alkyl, -OCO-lower alkyl, and halogen. Accordingly, the structures encompassed by independent claim 5 of the present invention are not described by Formula I of the '697 publication.

In view of the above, Applicants respectfully submit that there is no overlap of subject matter between Applicant's case and the '697 publication, therefore, the

structures described in the claims of the present invention cannot be the same as the structures disclosed in the '697 publication. Accordingly, there should be no remaining issue under 35 U.S.C. §102(e), §102 (f) or §102(g) referenced against Applicant. Therefore, Applicants respectfully submit that the Examiner's rejection be withdrawn.

E. Response in anticipation of potential 102(a) obviousness-type double patenting rejection

As indicated above, during the in-person interview with Examiner Chang on July 29, 2008, the Examiner indicated that while Applicants' submissions may clear the 102(a) anticipation and the 102(e), (f) or (g) issues, the Examiner may have to issue a new rejection based on a 35 U.S.C. § 102(a) obviousness-type double patenting, unless Applicants submission contains a statement indicating that US Patent Application Publication No. 2004/0077697 is abandoned and that no continuation applications have been filed.

In response, Applicants hereby declare that U.S. Patent Application Publication No. 2004/0077697 (U.S. Serial No. 10/470,917) is abandoned and that no continuation applications, divisional; applications, or continuation in-part applications have been filed off of the '697 publication.

III. CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims. A check in the amount of \$1,860.00 is enclosed herewith for the fee due for submission the Request for Continued Examination and for the fee due for a petition for 3-month extension of time. It is believed that no additional fees are due for this submission. However, if it is determined that any fees are due or that any fee has been overpaid, the Commissioner for Patents is hereby authorized to charge said fees or credit any overpayments to Deposit Account No. 50-0552.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

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